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PATENT
Attorney Docket No. MTP-024

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Watkins et al.
SERIAL NO.: 09/709,947 GROUP NO.: 1642
FILING DATE: November 10, 2000 EXAMINER: Alana M. Harris
TITLE: Materials and Methods for Detection and Treatment of Breast Cancer

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 6th day of April, 2004.


Mary E. Higdon

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith is/are:

1. Transmittal Form (1 page);
2. Fee Transmittal Form (1 page);
3. Supplemental Information Disclosure Statement (2 pages);
4. Supplemental Form PTO-1449 (4 pages);
5. Copies of cited references (AD-AK, BD-BJ, CCE-CCCK, and CP);
6. Check for \$180.00; and
7. Return receipt postcard.



TRANSMITTAL FORM

Application Serial Number	09/709,947
Filing Date	November 10, 2000
First Named Inventor	Watkins et al.
Group Art Unit	1642
Examiner Name	Alana M. Harris
Attorney Docket No.	MTP-024
Patent No.	Not applicable
Issue Date	Not applicable

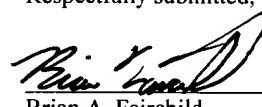
ENCLOSURES (check all that apply)

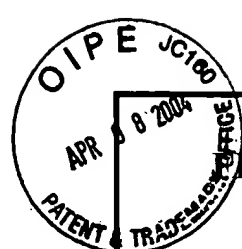
<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form <input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____] <input type="checkbox"/> Petition for Extension of Time <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application (PTO-1553) <input type="checkbox"/> Formal Drawing(s) <input type="checkbox"/> Request For Continued Examination (RCE) Transmittal <input type="checkbox"/> Power of Attorney (Revocation of Prior Powers) <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application <input type="checkbox"/> Small Entity Statement <input type="checkbox"/> CD(s) for large table or computer program <input type="checkbox"/> Amendment After Allowance <input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences <input type="checkbox"/> Appeal Brief (in triplicate) <input type="checkbox"/> Status Inquiry <input checked="" type="checkbox"/> Return Receipt Postcard <input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8 <input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8 <input type="checkbox"/> Additional Enclosure(s) (please identify below)
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CORRESPONDENCE ADDRESS

Direct all correspondence to: Patent Administrator
Testa, Hurwitz & Thibault, LLP
High Street Tower
125 High Street
Boston, MA 02110
Tel. No.: (617) 248-7000
Fax No.: (617) 248-7100

SIGNATURE BLOCK

Respectfully submitted,

Date: April 6, 2004
Reg. No. 48,645
Tel. No.: (617) 248-7697
Fax No.: (617) 248-7100
Brian A. Fairchild
Attorney for the Applicants
Testa, Hurwitz & Thibault, LLP
High Street Tower
125 High Street
Boston, MA 02110



FREE TRANSMITTAL
FY 2004

Complete if Known

Application Serial Number	09/709,947
Filing Date	November 10, 2000
First Named Inventor	Watkins
Group Art Unit	1642
Examiner Name	Alana M. Harris
Attorney Docket No.	MTP-024

METHOD OF PAYMENT

1. ☒ Payment Enclosed:
☒ Check ☐ Money Order ☐ Other
2. ☒ The Commissioner is hereby authorized to credit or charge any fee indicated below for this submission to Deposit Account No. 20-0531.
☐ Required Fees (copy of this sheet enclosed).
☒ Additional fee required under 37 CFR 1.16 and 1.17.
☒ Overpayment Credit.
3. ☐ Applicant claims small entity status.

FEE CALCULATION

1. FILING FEE

Large Entity

Fee (\$)	Fee Description	Fee Paid
770	Utility filing fee	
340	Design filing fee	
160	Provisional filing fee	

Number Filed	Number Extra	Rate	Amount
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Total Claims - 20 = x \$ 18.00 =

Independent Claims - 3 = x \$ 86.00 =

☐ Multiple Dependent Claim(s), if any \$290.00 =

TOTAL:
SMALL ENTITY DISCOUNT:
SUBTOTAL (1) (\$) .00

2. AMENDMENT CLAIM FEES

Claims Remaining After Amend.	Highest No. Previously Paid For	Present Extra	Rate	Fee Paid
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Total - = x \$ 18.00 =

Indep. - = x \$ 86.00 =

☐ First Presentation of Multiple Dep. Claim + \$290.00 =

TOTAL: (\$)
SMALL ENTITY DISCOUNT: (\$)
SUBTOTAL (2) (\$) .00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee (\$)	Small Entity Fee (\$)	Fee Description	Fee Paid
130	65	Surcharge - late filing fee or oath	
50	25	Surcharge - late provisional filing fee or cover sheet	
130	130	Non-English specification	
2,520	2,520	Request for ex parte reexamination	
110	55	Extension for reply within first month	
420	210	Extension for reply within second month	
950	475	Extension for reply within third month	
1480	740	Extension for reply within fourth month	
2010	1005	Extension for reply within fifth month	
330	165	Notice of Appeal	
330	165	Filing a brief in support of an appeal	
290	145	Request for oral hearing	
130	130	Petitions to the Commissioner	
180	180	Submission of Information Disclosure Statement	180.00
770	385	Filing a submission after final rejection (37 CFR 1.129(a))	
770	385	For each additional invention to be examined (37 CFR 1.129(b))	
100	100	Certificate of Correction for applicant's error	
110	55	Submission of Terminal Disclaimer	
Other fee (Specify)			
Other fee (Specify)			

SUBTOTAL (3) (\$) 180.00

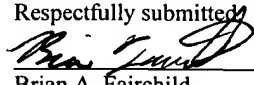
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SUBTOTAL (2) .00
SUBTOTAL (3) 180.00

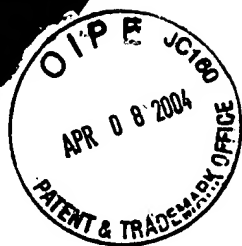
TOTAL (\$) 180.00

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Respectfully submitted,

Date: April 6, 2004
Reg. No.: 48,645
Tel. No.: (617) 248-7697
Fax No.: (617) 248-7100
Brian A. Fairchild
Attorney for the Applicants
Testa, Hurwitz & Thibault, LLP
High Street Tower-125 High Street
Boston, MA 02110



PATENT
Attorney Docket No. MTP-024

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Watkins *et al.*
SERIAL NO.: 09/709,947 GROUP NO.: 1642
FILING DATE: November 10, 2000 EXAMINER: Alana M. Harris
TITLE: Materials and Methods for Detection and Treatment of Breast Cancer

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

The Office Action of September 25, 2003, invited Applicants to resubmit documents AD-AK, BD-BJ, CCE-CCCK, and CP. In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby resubmit the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**

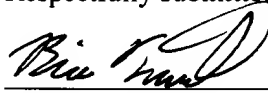
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application. Please charge any additional fee or credit any overpayment to deposit account 20-0531.

Date: April 6, 2004
Reg. No. 48,645
Tel. No.: (617) 248-7697
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3041687_1

Respectfully submitted,



Brian A. Fairchild
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125 High Street
Boston, Massachusetts 02110



FORM PTO - 1449				ATTORNEY DOCKET NO.: MTP-024					
SUPPLEMENTAL				APPLICANTS: Watkins et al.					
INFORMATION DISCLOSURE STATEMENT				SERIAL NO.: 09/709,947					
				FILING DATE: November 10, 2000 GROUP: 1642					
U.S. PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE		
	AD	5,342,764	30-Aug-94	Johnson et al.	435	252.3			
	AE	5,719,060	17-Feb-98	Hutchens et al.	436	174			
	AF	5,792,664	11-Aug-98	Chait et al.	436	89			
	AG	5,962,242	05-Oct-99	Klug	435	7.93			
	AH	6,197,525	06-Mar-01	Yao et al.	435	4			
	AI	6,225,047	01-May-01	Hutchens et al.	210	656			
	AJ	6,287,521	11-Sep-01	Quay et al.	422	101			
	AK	6,410,692	25-Jun-02	Stevens	530	388.25			
FOREIGN PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	BD	196 32 521 A	19-Feb-98	DE					
	BE	WO 99/39204	05-Aug-99	PCT					
	BF	AU 720626	19-Feb-98	AU					
	BG	WO 01/36977 A2	25-May-01	PCT					
	BH	WO 01/36977 A3	25-May-01	PCT					
	BI	WO 01/36470 A2	25-May-01	PCT					
	BJ	WO 01/36470 A3	25-May-01	PCT					
OTHER ART, JOURNAL ARTICLES, ETC.									
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)								
	CCE	Aleynik et al., "Increased circulating products of lipid peroxidation in patients with alcoholic liver disease," <u>Alcohol Clin. Exp. Res.</u> , 22(1):192-196 (Feb. 1998).							
	CCF	Chong et al., "Protein profiles and identification of high performance liquid chromatography isolated proteins of cancer cell lines using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry," <u>Rapid Commun. Mass. Spectrom.</u> , 12(24):1986-1993 (1998).							
EXAMINER					DATE CONSIDERED				



FORM PTO - 1449		ATTORNEY DOCKET NO.: MTP-024
SUPPLEMENTAL		APPLICANTS: Watkins et al.
INFORMATION DISCLOSURE STATEMENT		SERIAL NO.: 09/709,947
		FILING DATE: November 10, 2000 GROUP: 1642
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	CCG	Clements et al., "Biochemical characterization of patients and prenatal diagnosis of sialic acid storage disease for three families," <u>J. Inherit. Metab. Dis.</u> , 11(1):30-44 (1988).
	CCH	Cross et al., "The trans-spliceosomal U2 snRNP protein 40K of <i>Trypanosoma brucei</i> : cloning and analysis of functional domains reveals homology to a mammalian snRNP protein," <u>The EMBO Journal</u> , 12(3):1239-1248 (1993).
	CCI	Davies, H., "ProteinChip™ Case Study: Identification of a Novel Ligand," http://www.ciphergen.com , (June 16, 1999).
	CCJ	"Discovery of Protein Biomarkers and 'Phenomic Fingerprints' Using SELDI ProteinChip™ System," http://www.ciphergen.com , downloaded January 18, 2000.
	CCK	Fury et al., "Thirteen Anti-Sm Monoclonal Antibodies Immunoprecipitate the Three Cytoplasmic snRNP Core Protein Precursors in Six Distinct Subsets," <u>Journal of Autoimmunity</u> , 12:91-100 (1999).
	CCL	Gottschalk et al., "Identification by mass spectrometry and functional analysis of novel proteins of the yeast [U4/U6·U5] tri-snRNP," <u>The EMBO Journal</u> , 18(16):4535-4548 (1999).
	CCM	Gozani et al., "Evidence that sequence-independent binding of highly conserved U2 snRNP proteins upstream of the branch site is required for assembly of spliceosomal complex A," <u>Genes & Development</u> , 10:233-243 (1996).
	CCN	Habets et al., "Mapping of B Cell Epitopes on Small Nuclear Ribonucleoproteins that React with Human Autoantibodies as well as with Experimentally-Induced Mouse Monoclonal Antibodies," <u>The Journal of Immunology</u> , 143(8):2560-2566 (October 15, 1989).
	CCO	Halliday et al., "Differentiation of human tumors from nonmalignant tissue by natural-abundance ¹³ C NMR spectroscopy," <u>Magn. Reson. Med.</u> , 7(4):384-411 (1988).
	CCP	Harper et al., "RNA binding specificity of a <i>Drosophila</i> snRNP protein that shares sequence homology with mammalian U1-A and U2-B" proteins," <u>Nucleic Acids Research</u> , 20(14):3645-3650(1992).
	CCQ	Hong et al., "Association of U2 snRNP with the spliceosomal complex E," <u>Nucleic Acid Research</u> , 25(2):354-361 (1997).
	CCR	Jellum et al., "Profiling cells and body fluids – chromatography and two-dimensional electrophoresis as complementary techniques," <u>J. Chromatogr.</u> , 488(1):105-127 (March 17, 1989).
	CCS	Jellum, E., "Multi-Component Analyses of Human Body Fluids and Tissues in Health and Disease Using Capillary Gas Chromatography -Mass Spectrometry and High-Resolution Two-Dimensional Electrophoresis," <u>Journal of Chromatography</u> , 239:29-37 (1982).
	CCT	Jellum et al., "Clinical Applications of Two-Dimensional Electrophoresis," <u>Clin. Chem.</u> , 28(4):876-883 (1982).
EXAMINER		DATE CONSIDERED



SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTORNEY DOCKET NO.: MTP-024 APPLICANTS: Watkins et al. SERIAL NO.: 09/709,947 FILING DATE: November 10, 2000 GROUP: 1642
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	CCU	Kramer et al., "Combined Biochemical and Electron Microscopic Analyses Reveal the Architecture of the Mammalian U2 snRNP," <u>The Journal of Cell Biology</u> , 145(7):1355-1368 (June 28, 1999).
	CCV	Lalioti et al., "The Gene for Human U2 snRNP Auxiliary Factor Small 35-kDa Subunit (<i>U2AF1</i>) Maps to the Progressive Myoclonus Epilepsy (EPM1) Critical Region on Chromosome 21q22.3," <u>Genomics</u> , 33:298-300 (1996).
	CCW	Lamond et al., "Probing the Structure and Function of U2 snRNP with Antisense Oligonucleotides Made of 2'-OMe RNA," <u>Cell</u> , 58:383-390 (July 28, 1989).
	CCX	Leaves et al., "Pyrolysis mass spectrometry in epidemiological and population genetic studies of <i>Haemophilus influenzae</i> ," <u>J. Med. Microbiol.</u> , 46(3):204-207 (1997).
	CCY	Lim et al., "Altered hydroxylation of estrogen in patients with postmenopausal osteopenia," <u>J. Clin. Endocrinol. Metab.</u> , 82(4):1001-1006 (April 1997).
	CCZ	Loo et al., "High sensitivity mass spectrometric methods for obtaining intact molecular weights from gel-separated proteins," <u>Electrophoresis</u> , 20:743-748 (1999).
	CCCA	Lollo et al., "Improved two-dimensional gel electrophoresis representation of serum proteins by using ProtoClear™," <u>Electrophoresis</u> , 20:854-859 (1999).
	CCCB	Ogorzalek Loo et al., "Sensitivity and mass accuracy for proteins analyzed directly from polyacrylamide gels: Implications for proteome mapping," <u>Electrophoresis</u> , 18:382-390 (1997).
	CCCC	Ogorzalek Loo et al., "Mass Spectrometry of Proteins Directly from Polyacrylamide Gels," <u>Anal. Chem.</u> , 68:1910-1917 (1996).
	CCCD	Osin et al., "Experimental pathology and breast cancer genetics: new technologies," <u>Recent Results Cancer Res.</u> , 152:35-48 (1998).
	CCCE	Ostergaard et al., "Proteome profiling of bladder squamous cell carcinomas: identification of markers that define their degree of differentiation," <u>Cancer Res.</u> , 57(18) 4111-4119 (September 15, 1997).
	CCCF	Rohde et al., "Comparison of protein mixtures in aqueous humor by membrane preconcentration - capillary electrophoresis - mass spectrometry," <u>Electrophoresis</u> , 19:2361-2370 (1998).
	CCCG	Schuhmacher et al., "Investigations concerning the potential for using ¹ H NMR relaxometry or high-resolution spectroscopy of plasma as a screening test for malignant lung disease," <u>Magn. Reson. Med.</u> , 13(1):103-132 (1990).
	CCCH	Spector et al., "Differences in snRNP Localization Between Transformed and Nontransformed Cells," <u>Molecular Biology of the Cell</u> , 3:555-569 (May 1992).
	CCCI	Thiede et al., "Identification of human myocardial proteins separated by two-dimensional electrophoresis with matrix-assisted laser desorption/ionization mass-spectrometry," <u>Electrophoresis</u> , 17(3):588-599 (1996).
EXAMINER		DATE CONSIDERED

[illegible]

SUPPLEMENTAL

INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: MTP-024

APPLICANTS: Watkins et al.

SERIAL NO.: 09/709,947

FILING DATE: November 10, 2000 GROUP: 1642

EXAM.
INIT.

OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)

CCCJ

Weekes et al., "Bovine dilated cardiomyopathy: Proteomic analysis of an animal model of human dilated cardiomyopathy," *Electrophoresis*, 20:898-906 (1999).

CCCK

Xu et al., "Synthetic Lethality of Yeast *slt* Mutations with U2 Small Nuclear RNA Mutations Suggests Functional Interactions between U2 and U5 snRNPs That Are Important for Both Steps of Pre-mRNA Splicing," *Molecular and Cellular Biology*, 18(4):2055-2066 (April 1998).

CP

Bazel et al., "Characterization of Purified Cathepsin D From Malignant Human Breast Tissue"
International Journal of Oncology 14: 315-319 (1999)

EXAMINER

DATE CONSIDERED

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